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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/624,915	07/22/2003	D. Russell Pflueger	D-3077	7109
33197	7590	02/23/2006	EXAMINER	
STOUT, UXA, BUYAN & MULLINS LLP			PATEL, NIHIR B	
4 VENTURE, SUITE 300			ART UNIT	
IRVINE, CA 92618			PAPER NUMBER	

3743

DATE MAILED: 02/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

SP

Office Action Summary	Application No.	Applicant(s)	
	10/624,915	PFLUEGER ET AL.	
	Examiner	Art Unit	
	Nihir Patel	3743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 7th, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-55 and 66-92 is/are pending in the application.
- 4a) Of the above claim(s) 69 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 52-55, 66-68 and 70-92 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>05.10.2005</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of figures 7 and 26 in the reply filed on December 7th, 2005 is acknowledged. Claim 69 (**claim 69 defines tube and the specification on figures 7 and 26 does not describe a tube**) is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 7th, 2005.

Drawings

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because the current drawings (**especially figure 26**) fails to facilitate understanding of the invention. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim **52-55, 66-68, 70, 71, 73-77, 79 and 80** are rejected under 35 U.S.C. 102(b) as being anticipated by Conrad et al. (US 6,250,307). **Referring to claim 52**, Conrad discloses a

method step that comprises providing an appliance in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal (see **figures 6, 7, 11, 12, 22 and 23**), the appliance so provided being effective in treating at least one of sleep apnea and snoring (see abstract).

Referring to claim 53, Conrad discloses a method step wherein the appliance, when so provided, is effective in maintaining patency of the oropharyngeal region during natural sleep of the human or animal without causing substantial interference with at least one natural function of the epiglottis (see **column 4 lines 44-55**).

Referring to claim 54, Conrad discloses a method step that includes inserting the appliance into the oropharyngeal region while the appliance is in a first configuration and allowing the appliance to reconfigure to a second configuration within or in proximity to the oropharyngeal region (see **column 4 lines 5-15**).

Referring to claim 55, Conrad discloses a method of inserting the appliance into the oropharyngeal region through a mouth or a nose of a human or animal (see **figure 3**).

Referring to claim 66, Conrad discloses a method step of placing the appliance in or beneath the mucosal layer of the lateral and posterior walls of the oropharyngeal region (see **figures 6, 7, 11, 12, 22 and 23**).

Referring to claim 67, Conrad discloses a method step of placing the appliance completely across the posterior wall of the oropharyngeal region (see **figures 6, 7, 11, 12, 22 and 23**).

Referring to claim 68, Conrad discloses a method step of providing the appliance in a deformed first configuration, inserting the appliance into the oropharyngeal region and allowing

the appliance to configure to a deployed second configuration within the oropharyngeal region (see column 5 lines 51-67 and column 6 lines 1-9).

Referring to claim 70, Conrad discloses a method step of providing at least two substantially laterally positioned elements substantially longitudinally spaced apart across the posterior wall of the oropharyngeal region (see figures 6, 7, 11, 12, 22 and 23).

Referring to claim 71, Conrad discloses a method step wherein the at least two elements are coupled together (see figures 17 and 18).

Referring to claim 73, Conrad discloses a method step wherein the appliance has a lateral dimension and a longitudinal dimension perpendicular to the lateral dimension which is less than the lateral dimension when the appliance is so provided (see figures 17 and 18).

Referring to claim 74, Conrad discloses a method wherein the appliance is sized and structured so that each of the at least two elements extend across the posterior wall and at least a portion of the lateral walls when the appliance is so provided (see figure 11).

Referring to claim 75, Conrad discloses a method wherein the appliance is sized and structured so that the at least two elements extend across the posterior wall and at least a portion of the lateral walls when the appliance is so provided (see figure 11).

Referring to claim 76, Conrad discloses a method step wherein the appliance has an open concave loop when so provided (see figure 11).

Referring to claim 77, Conrad discloses a method step wherein the appliance, when so provided, is effective to support or reinforce the oropharyngeal region without reacting with tissue in the oropharyngeal region (see figure 11).

Referring to claim 78, Conrad discloses a method step wherein the appliance comprises resilient wire (see figure 17 and 18).

Referring to claim 79, Conrad discloses a method step wherein the appliance is made of biocompatible metal (see column 5 lines 50-55).

Referring to claim 80, Conrad discloses a method step wherein the appliance is made of an elastic spring memory material (see column 5 lines 50-55).

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims **82 through 90** are rejected under 35 U.S.C. 102(e) as being anticipated by Metzger et al. (US 2003/0149488). **Referring to claim 82**, Metzger discloses an apparatus that comprises an appliance **110** (see figures 6 and 7) comprising two elongated curved elements each having a substantially circular dimension between a first end and a second end extending through more than 90 degrees of a circle (see figures 6 and 7, pages 3 and 4 paragraphs 0041, 0042 and 0043; the plurality of braids make up the two elongated elements), the two elements being coupled together at respective first and second ends (see page 4 paragraph 0043), the appliance being sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall and,

when so placed, being effective in treating at least one of sleep apnea and snoring (**see figures 6 and 7**).

Referring to claim 83, Metzger discloses an apparatus wherein the substantially circular dimension between the first and the second ends extends through at least 180 degrees of a circle (**see figures 6 and 7**).

Referring to claim 84, Metzger discloses an apparatus wherein each of the curved elements has a curved length extending from the first end to the second end, and the first end and the second end defining a gap therebetween extending outwardly away from the first and second curved elements having length which is reduced relative to the curved length of each of the curved elements (**see figures 6 and 7**).

Referring to claim 85, Metzger discloses an apparatus wherein each of the two elongated elements comprises a resilient wire (**see page 4 paragraph 0043**).

Referring to claim 86, Metzger discloses an apparatus wherein the appliance comprises a substantially c-shaped structure (**see figures 6 and 7**).

Referring to claim 87, Metzger discloses an apparatus wherein the two elongated elements are portions of the same structure (**see figures 6 and 7**).

Referring to claim 88, Metzger discloses an apparatus wherein the appliance as a lateral dimension defined by the distance between the first and second ends and a maximum longitudinal dimension perpendicular to the lateral dimension which is less than the lateral dimension (**see figures 6 and 7**).

Referring to claim 89, Metzger discloses an apparatus wherein the appliance has a concave loop configuration when the appliance is so placed in an oropharyngeal region (see **figures 6 and 7**).

Referring to claim 90, Metzger discloses an apparatus wherein the appliance is made of a biocompatible material (see **page 3 paragraph 0042**).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims **72, 81, 91 and 92** are rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad (US 6,250,307) in view of Metzger et al. (US 2003/0149488). **Referring to claim 72**, Conrad discloses the applicant's invention as claimed with the exception of providing at least two elements that are portions of the same structure. Metzger discloses an apparatus that does provide at least two elements that are portions of the same structure. Therefore it would have been obvious to modify Conrad's invention by providing at least two elements that are portions

of the same structure as taught by Metzger in order to reduce airway collapse as a treatment for sleep apnea.

Referring to claims 81 and 92, Conrad discloses a method wherein the appliance can be made of nitinol (see column 7 lines 5-20).

Referring to claim 91, Conrad discloses a method step wherein the appliance is made of an elastic spring memory material (see column 5 lines 50-55).

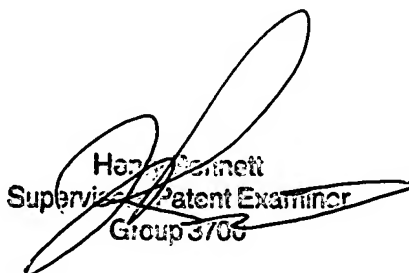
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nihir Patel
February 10th, 2006


Henry Bennett
Supervisor/Patent Examiner
Group 3703